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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/368,866 08/05/99 LINAS-BRUNET

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EXAMINER

DSWECKI, T

ART UNIT

PAPER NUMBER

1626

DATE MAILED:

12/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/368,866**

Applicant(s)

**Linus-Brunet et al.**

Examiner  
**Jane Oswecki**

Group Art Unit  
**1626**



☒ Responsive to communication(s) filed on Sep 5, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-26, 28-80, and 84-87 is/are pending in the application.

Of the above, claim(s) 73-80 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 5-7, 11-14, 30, 32, 36, 37, 45-47, 49, 51, 53, 55, 57, 59, 61, 63, and 64 are rejected.

☒ Claim(s) 2-4, 8-10, 15-26, 28, 29, 31, 33-35, 38-44, 48, 50, 52, 54, 56, 58, 60, is/are objected to.

☐ Claims 62, 64, 66-72 & 84-87 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*Jane Oswecki*  
JANE OSWECKI  
PATENT EXAMINER  
ART UNIT 1626

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

Claims 1-26, 28-80 and 84-87 are pending in the application. Claims 27 and 81-83 have been canceled by amendment; claim 87 has been added by amendment. Claims 73-80 are withdrawn from consideration by the examiner under 37 C.F.R. 1.142(b) as directed to non-elected subject matter.

#### *Election/Restriction*

Applicants' election with traverse in Paper No. 10 filed September 5, 2000, of Group II, claims 1-65, drawn to compounds of formula (I) having optionally substituted pyridinyl, benzopyridinyl, pyridinyloxy, benzopyridinyloxy and/or pyridinyl-methoxy groups alone or in combination with pyrazolyl, thiazolyl, thienyl, furanyl, indolyl and/or indolinyl groups in addition to the proline moiety, and claims 66-72 and 82-86 as commensurate in scope therewith, is acknowledged.

The traversal is made on several grounds, to wit: that Group II should include compounds of formula (I) in which  $R_{20}$  is Het or (lower alkyl)-Het and where the "Het" group is an optionally substituted pyridinyl or quinolyl; that instant claim 75 would be grouped with instant claim 74 in Group IX; that instant claim 82 would be grouped with instant claim 81 in Group XII; that no restriction should be made between the final product compounds of Groups I-VII and the intermediate compounds of Group XI; and that no restriction should be made between the final product compounds of Groups I-VII and the processes of Groups VIII-X.

With respect to the first ground for traversal, applicants' attention is directed to the

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definition of Group II in Paper No. 7 in which pyridinyl and quinolyl are included. Thus, this basis for traversal is moot. Applicants' second point is well taken, and Groups IX and X are hereby joined to form a new Group IX which includes instant claims 74, 74 and 80. To the extent of this joinder, the Restriction Requirement in Paper No. 7 is amended. Accordingly, Group X which appears in Paper No. 7 is stricken from the requirement. Applicants' third point is rendered moot by the Preliminary amendment of Paper No. 8 filed September 11, 2000.

Applicants' ground for traversing restriction between the final product compounds of Groups I-VII and intermediate compounds of Group XI is well taken. However, the entry of U.S. 5,164,402 as a basis for this restriction was in error, and the examiner regrets any inconvenience this may have caused. Applicants' attention is directed to the abstract for JP 05155827 included herewith, in which Ishikawa et al. teach the use of the same intermediate compounds as endothelin antagonists. Finally, with respect to the restriction between final product compounds and processes for preparing the same, it is noted that such condensation reactions are well-known in the art by applicants' own admission (Specification at page 30, line 14). Moreover, under the present election of Group II drawn to compounds, instant claims to processes are held withdrawn from consideration pending a determination of patentability of the elected compounds. At such time as the elected compounds may be found allowable, claims to processes as commensurate in scope with the then-allowable compounds will be rejoined under the Court's holding in In re Ochiai et al., 37 U.S.P.Q.2d 1127 (CAFC 1995) and In re Brouwer, 37 U.S.P.Q.2d 1663 (Fed. Cir. 1996).

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Since Applicants have not acknowledged that all inventions are indistinct and a prior art reference for one is a reference for all, the requirement for restriction is still deemed proper and is therefore made FINAL. It is suggested that, in order to advance prosecution, all non-elected subject matter be canceled from the instant application with the response to this Office action.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following quotation of 35 U.S.C. 112, second paragraph, forms the basis for all lack of clarity rejections found within this Office action:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”

Claims 1, 5-7, 11-14, 30, 32, 36, 37, 45-47, 49, 51, 53, 55, 57, 59, 61, 63 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has the transitional word “comprising” which is open-ended. Especially with respect to claims for compounds, the word “comprising” renders the claim indistinct (see MPEP 2111.03).

Claims 1, 5-7, 11-14 and 47 are confusing with respect to the definitions for “B” substituents. While a “B” substituent is clearly defined as “...an acyl derivative...”, it is next defined as “...a carboxyl...” where an ester is shown; as “...an amide...” where a carboxamide is shown; as “...a thioamide...”; and as “...a sulfonyl...”. It is suggested that the word “derivative”

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be inserted after each of these terms in these claims and in all occurrences for purposes of clarity and in keeping with the term "acyl derivative".

Claim 30 is confusing because it refers back to itself for a definition.

Claim 32 lacks antecedent basis in claim 29 for the substituent "halo".

Claims 36, 37, 45 and 46 are confusing in that claim 1, from which each of these claims ultimately depends, structurally depicts amino acid segments designated as P1, P2 and P3. However, claims 36 and 37 define P1 as a cyclobutyl or cyclopropyl ring, and claims 45 and 46 define P1 as a cyclopropyl ring. This is confusing where the P1 segment in independent claim 1 has amino and carboxyl moieties in addition to the ring structure.

Regarding claim 47, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 49, 51, 53, 55, 57, 59, 61 and 63 are rejected for listing compounds by compound numbers drawn from a table rather than by nomenclature or structure. These claims fail to "particularly pointing out and distinctly claim" the subject matter intended by applicants.

Claim 65 is made confusing by the introduction of substituents "X" and "Z" where such substituents are not found in claim 1 from which claim 65 ultimately depends. By definition in independent claim 1, substituent "X" must always be a nitrogen atom. Substituent "Z" appears to be a part of the definition for substituent "R<sup>2</sup>" in claim 1. It is suggested that these substituents be labeled consistently in all claims.

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Appropriate correction is required in all instances.

***Provisos***

The provisos to claim 1 are noted. If such are included to bring the claims outside the scope of known prior art, such art should be provided to ensure complete consideration. If the provisos are included to eliminate compounds known to lack the disclosed utility, such should be stated on the record.

***Claim Objections***

Claims 1, 15, 19, 29, 46, 50, 62 and 87 are objected to because of the following informalities: claim 1, last three lines, in the definition of "Het" is objected to for embracing heterocycles that are non-elected under the terms of the Restriction Requirement. Likewise, claims <sup>OK</sup>62 and <sup>OK</sup>87 also contain non-elected subject matter, i.e., heterocycles outside those listed in Group II of Paper No. 7.

<sup>OK OK OK</sup> Claims 15, 19 and 46 include parentheticals for terms defined in the specification. The use of parentheses implies that additional or explanatory information is contained therein, while claims are to be written in a clear and concise manner. It is suggested that these parentheticals be deleted from the claims.

<sup>-OK</sup> Claim 29 has a typographical error in line 4, and claim 50 at page 14 of Paper No. 8 requires deletion of the word "and" in the line prior to "Cpd #203" since only one compound remains within that claim.

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Claims 2-4, 8-10, 15-26, 28, 29, 31, 33-35, 38-44, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66-72 and 84-87 also are objected to for depending from a rejected base claim.

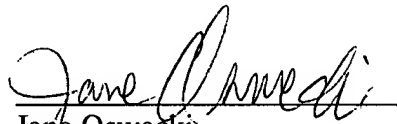
Appropriate correction is required in all instances.

***Telephone Inquiry Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Oswecki whose telephone number is (703)305-7152. The examiner can normally be reached Monday through Thursday from 7:30 AM to 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (703)308-4537. The telephone number for this Group is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-1235.

  
Jane Oswecki  
Patent Examiner  
Art Unit 1626

30 November 2000